

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ralph M. ELLISON et al.
Title: COMPOSITIONS AND METHODS FOR THE TREATMENT OF
PRIMARY AND METASTATIC NEOPLASTIC DISEASES USING
ARSENIC COMPOUNDS
Appl. No.: 10/649,944
Filing Date: 08/28/2003
Examiner: Not yet assigned
Art Unit: 1614

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003*.

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/173,531, filed 10/15/1998. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any

rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language documents is explained in the parent application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

By 

Date December 23, 2003

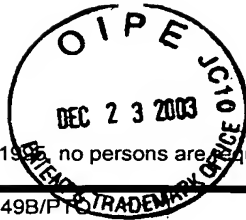
FOLEY & LARDNER

Customer Number: 22428

Telephone: (202) 672-5404

Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: December 23, 2003

(use as many sheets as necessary)

Sheet 1 of 6

Complete if Known

Application Number	10/649,944
Filing Date	08/28/2003
First Named Inventor	Ralph M. ELLISON
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	077319-0384

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		132,275		Gettings	10/15/1872	
		232,807		Dennett	10/05/1886	
		3,700,498		Kanazawa et al.	10/24/72	
		4,497,780		Barin et al.	02/05/85	
		5,759,837		Kuhajda et al.	06/02/98	
		09/110,366		Lu	Filed: 7/6/98	
		09/189,965		Warrell Jr. et al.	Filed: 11/10/98	
		08/702,011		Zhang	Filed: 8/23/96	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
			JP-51-88620			03/08/76		
			WO 95/01789			1/19/95		
			CN 1133725 A			10/23/96		
			CN 1131037 A			9/18/96		
			CN 1122700 A			5/22/96		
			CN 1081104 A			1/26/94		
			CN 1119113 A			3/27/96		
			CN 1061908 A			6/17/92		
			CN 1121807 A			5/8/96		
			CN 1079391 A			12/15/93		
			WO 94/02108			2/3/94		
			FR 2 539 993 A1			3/31/94		
			DE 43 17 331 A1			12/1/94		
			WO 95/22336			8/24/95		
			LV 11667 B			6/20/97		
			JP 51-88620			3/8/76		
			CN 1061908A			6/17/92		
			CN 1081104A			1/26/94		
			WO 94/02108			2/3/94		
			FR 2 539 993 A1			3/31/94		
			WO 95/01789			1/19/95		
			WO 95/22336			8/24/95		
			CN 1119113A			3/27/96		
			CN 1121807 A			5/8/96		
			CN 1122700 A			5/22/96		
			CN 1131037 A			9/18/96		
			CN 1133725 A			10/23/96		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

MODIFIED PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: December 23, 2003 <i>(use as many sheets as necessary)</i>		Application Number	10/649,944
		Filing Date	08/28/2003
		First Name of Inventor	Ralph M. ELLISON
		Group Art Unit	1614
		Examiner Name	Unassigned
		Attorney Docket Number	077319-0384
Sheet	2	of	6

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		"Arsen (III) – Sulfid As ₂ S ₂ ", Gmelin's Arsenic, 8 th . Edition, 17:422-433, 1952.	
		"Diarsendisulfid As ₂ S ₂ ", Gmelin's Arsenic, 8 th . Edition, 17:412-422, 1952.	
		"Goodman & Gilman's The pharmacological basis of therapeutics", 9 th Edition, McGraw-Hill, Health Professions Division, pp. 1659-1662	
		"Inorganic Arsenic Compounds Other Than Arsine Health and Safety Guide, Health and Safety Guide No. 70", WHO, Geneva, 1992	
		"Xionghuang Realgar", Chinese Pharmacopia (1), Guangdong Science and Technology Publishing House, China, pp. 298-299, 1995	
		Akao et al. "Arsenic Induces Apoptosis in B-cell Leukemic Cell Lines in Vitro: Activation of Caspases and Down-regulation of Bcl-2 Protein", British J of Hematology, 102. 1055-1060, 1998.	
		Andre et al., "The PML and PML/RAR α Domains: from autoimmunity to molecular oncology and from retinoic acid to arsenic", Experimental Cell Research, 229:253-260, 1996.	
		Arsenic, Environmental Health Criteria 18, Geneva: WHO, 1981	
		Chemical Abstract, 63-Pharmaceuticals 11:317, #111:219272j and 111:219276p, 1987-1991.	
		Chen et al., "In vitro studies on cellular and molecular mechanisms of arsenic trioxide (As ₂ O ₃) in the treatment of acute promyelocytic Leukemia: As ₂ O ₃ induces NB ₄ cell apoptosis with down regulation of Bcl-2 expression and modulation of PML-RAR α /PML proteins", Blood 88(3): 1052-1061, 1996	
		Chen et al., "Use of Arsenic Trioxide (As ₂ O ₃) in the Treatment of Acute Promyelocytic Leukemia (APL):I. As ₂ O ₃ Exerts Dose-Dependent Dual Effects on APL Cells" Blood 89(9):3345-3353, 1997	
		Chung et al., "Influence for Carcinoma Cell and Lymphatic cell of Acetyl Arsonate", Yakhak Hoeji 40(5):599-607, 1996.	
		Cutler et al., Article IV, American Journal of the Medical Sciences, pp. 74-84.	
		Cuzick et al., "Medicinal arsenic and internal malignancies", Br. J. Cancer, 45:904-911, 1982	

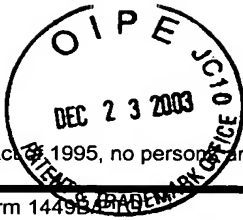
Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449SA

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: December 23, 2003

(use as many sheets as necessary)

Sheet 3 of 6

Complete if Known

Application Number	10/649,944
Filing Date	08/28/2003
First Named Inventor	Ralph M. ELLISON
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	077319-0384

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		De The, "L'oxyde d'arsenic: après l'acide retinoïque, un nouveau traitement cible de la leucémie aigue promyelocytaire" medicine/sciences; 13: 867-71, 1997	
		Dictionary of Inorganic Compounds, Vol. 1, Ac-C ₁₀ , IC-000667-IC-000671	
		Flamigni et al., "Effect of Sodium Arsenite on the Induction and Turnover of Ornithine Decarboxylase Activity in Erythroleukemia Cells" Cell Biochemistry and Function 7:213-217, 1989	
		Fluka, 1995/96 Catalog: 152-153	
		Forkner et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour. A.M.A. 97(1)3-5, 1931.	
		Germolec et al., "Arsenic induces over expression of growth factors in human keratinocytes", Toxicology and Applied Pharmacology, 141:308-318, 1996.	
		Huang et al., 1995, "The Clinical Study of QINGDAI Tablet For Treating Acute Promyelocytic Leukemia" China Magazine of Hematology, 16(1):26.	
		Ishinishi N. et al., "Study on Chronic Toxicity of Arsenic Trioxide in Rats with Special Reference to the Liver Damages" Fukuoka Acta Medicine, 71:27, 1980.	
		Kasper et al., "Hepatic Angiosarcoma and bronchioloalveolar carcinoma induced by Fowler's solution", JAMA 252(24):3407-3408, 1984.	
		Kerkvliet et al., "Immunotoxicology Studies of Sodium Arsenate-effects of Exposure on Tumor Growth and Cell-mediated Tumor Immunity", J. Environmental Pathology and Toxicology 4:65-79, 1980.	
		Konig et al., "Comparative Activity of Melarsoprol and Arsenic Trioxide in Chronic B-Cell Leukemia Lines", Blood 90(2):562-570, 1997.	
		Kwong et al., "Delicious Poison: Arsenic Trioxide for the treatment of Leukemia", Blood 89:3487-8, 1997.	
		Lee et al., "Induction of Gene Amplification by Arsenic", Science, 241: 79-81, 1988.	
		Li et al. "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988.	
		Lu et al., "Effective treatment of AML-M3 (APL) and their remission maintenance with Realgar: A pilot clinical and laboratory study on 38 patients", Blood 90(10 Suppl. 1 part 1):416A, #1849, 1997.	

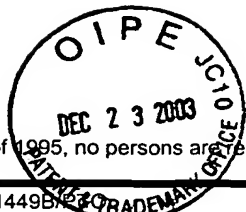
Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B, PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: December 23, 2003

(use as many sheets as necessary)

Complete if Known

Application Number	10/649,944
Filing Date	08/28/2003
First Named Inventor	Ralph M. ELLISON
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	077319-0384

Sheet 4 of 6

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		Lu et al., "Study of Realgar in the treatment of acute promyelocytic Leukemia (APL)- a pilot clinical and laboratory study on 38 patients", China-Korea Medical Conference '97 1997.	
		Mervis, "Ancient remedy performs new tricks", Science 273: 578, 1996.	
		Monfardini et al., "Survival in chronic myelogenous leukemia: influence of treatment and extent of disease at diagnosis", Cancer, 31:492-501, 1973.	
		Neubauer, "Arsenic Cancer: a review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947.	
		Pershagen et al., "On the pulmonary tumorigenicity of arsenic trisulfide and calcium arsenate in hamsters", Cancer Letter, 27:99-104, 1985.	
		Pories et al., "Trace Elements that Act to Inhibit Neoplastic Growth", Annals New York Academy of Sciences, 199: pp 265-273, 1972.	
		Qi and Bi, "Method for removing As ₂ O ₃ from Realgar", Chung Yao Tung Pao, 8(5):21-22, 1983	
		Reichl et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol., Suppl. 13. p. 363-65, 1989.	
		Remington's Pharmaceutical Sciences, Mach Publishing Co., Easton, PA, p. 1570-80, 1990.	
		Schenk, Handbook of Preparative Inorganic Chemistry, 1:603, G. Brauer, Ed., Academic press, New York, 2 nd Ed. 1963.	
		Shen et al., "Use of arsenic trioxide (As ₂ O ₃) in the treatment of acute promyelocytic Leukemia (APL):II. Clinical efficacy and pharmacokinetics in relapsed patients", Blood 89(9):3354-3360, 1997.	
		Shibuya, "Studies on Experimental Arsenious Acid Poisoning", Tokyo Jikeikai Ika Daigaku Zasshi 86(4):653, 1971.	
		Soignet et al., "Complete Remission after Treatment of Acute Promyelocytic Leukemia with Arsenic Trioxide", J of Medicine 339:19, 1998.	
		Stephens et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia" Ann. Intern. Assoc 9:1488-1502, 1936.	
		Suehiro Shimotsuura et al., "Studies on the Antineoplastic Actions of As ₂ O ₃ ", Shikwa Gakuho 86:1237-1253, 1986.	

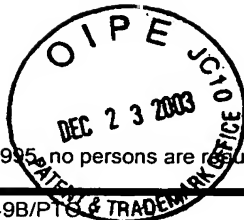
Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

MODIFIED PTO/SB/08 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO & TRADEMARK OFFICE

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: December 23, 2003

(use as many sheets as necessary)

Complete if Known

Application Number	10/649,944
Filing Date	08/28/2003
First Named Inventor	Ralph M. ELLISON
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	077319-0384

Sheet 5 of 6

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		Sun et al., "Ai Ling #1 and Traditional Chinese Medicine in the Treatment of 32 patients with Acute Promyelocytic Leukemia", Chinese J. of Traditional Chinese and Western Medicine 1(3), 1992.	
		Treleaven et al., "Arsenic and Ayurveda" Leukemia and Lymphoma 10:343-345, 1993.	
		USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc. Rockville, MD, p. 59, 11/1994	
		Wang et al., "Arsenic and the Treatment of Leukemia", J. Harbin Medical Univ. 31:5 428-429, 1997.	
		Wang et al., "Studies on chemically preventing Leukemia", Chung Hua Chung Liu Tsa Chih, 11(3):207-210, 1989.	
		Xiang et al., 1995, "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229.	
		Yamamoto et al. "Tumorigenicity of inorganic arsenic compounds following intratracheal instillations to the lungs of hamsters", Int. J. Cancer, 40:220-223, 1987.	
		Yuan et al., "Research on traditional methods for Purifying Realgar", Chung Yao Tung Pao, 13(8): 23-26, 1988	
		Yuan et al., "Exploring methods for purifying Realgar", Chung Yao Tung Pao, 13(8): 17-21, 1988.	
		Zhang et al., "Traditional Chinese and Western Medicine in the Treatment of 27 patients with Malignant Lymphoma" Chinese J. Oncology 10:61-62, 1988.	
		Zhang et al. "Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 Patients", J. Harbin Medical Univ. 29(3): 243, 1995.	
		Zhang et al., "Clinical Study on the Treatment of Acute Promyelocytic Leukemia with Ai Ling #1", J of Traditional Chinese and Western Medicine 4(1):19, 1984.	
		Zhang et al., "Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide", Chinese J. of Hematology 17(2): 1996.	
		Zhang et al. "Discussion on methods for removing As involving use of yogurt", Zhongguo Zhongyao Zaohi, 20(9): 537, 1995.	
		Zhu et al., "Arsenic-induced PML targeting onto nuclear bodies: implications for the treatment of acute promyelocytic leukemia", Proc. Natl. Acad. Sci. 94:3978-3983, 19978.	

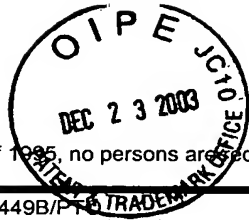
Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/P-T-5

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: December 23, 2003

(use as many sheets as necessary)

Complete if Known

Application Number	10/649,944
Filing Date	08/28/2003
First Named Inventor	Ralph M. ELLISON
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	077319-0384

Sheet 6 of 6

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		"Letter on Historical Facts Regarding the Development of Ai Ling. No. 1 and the Clinical Use of Arsenic Trioxide in the Treatment of Acute Promyelocytic Leukemia and a Study of its Mechanism" Heilongjiang Branch of the Chinese Medical Association, March 27, 1998.	
		Wang et al., "Arsenic Trioxide and Melarsprol Induced Programmed cell death in myeloid leukemia cell lines and function in PML and PNL-RAR α Independent Manner," Blood, 92(5):1497-1504, 1998.	
		Flamigni et al., "Effect of Sodium Arsenite on the Induction and Turnover of Ornithine Decarboxylase Activity in Erythroleukemia Cells", Cell Biochemistry and Function Vol. 7:213-217 (1989) © John Wiley & Sons Ltd. 1989	
		Reichi et al., "Effect of Arsenic on Cellular Metabolism After Single or Repeated Injection in Guinea Pigs" Arch. Toxicol., Suppl. 13, 363-365 (1989) © Springer Verlag 1989	
		Remington's Pharmaceutical Sciences, Mack Publishing Company, Easton PA, Chapter 85, pp. 1570-80, 1990.	
		"Inorganic Arsenic Compounds other than Arsine Health and Safety Guide, Health and Safety Guide No. 70, WHO, Geneva 1992.	
		Sun et al., "Ai Ling #1 and Traditional Chinese Medicine in the Treatment of 32 Patients with Acute Promyelocytic Leukemia, Chinese J. of Traditional Chinese and Western Medicine, pp. 170-171, Vol. 12, No. 3, 1992.	
		Treleaven et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, Vol. 10, pp. 343-345 © Harword Academic Publishers GmbH 1993	
		USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville Md., p. 59, November 1995	
		Fluka 1995/96 Catalog, pp. 152-153 July 1995	
		Wang et al., "Arsenic and the Treatment of Leukemia" J. Harbin Medical University, Vol. 31, No. 5, October 1997	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.